Dissolution test procedure:

United States Pharmacopeia XX, page 939, Mack Printing Co., Easton, Pa., 1980

Conditions:

USP Apparatus 2

Media: 900 ml simulated gastric fluid without enzymes

Rotation Speed: 50 RPM.

Apparatus 2—Use the assembly from Apparatus 1, except that a paddle formed from a blade and a shaft is used as the stirring element.[4] The shaft, 10±0.5 mm in diameter, is positioned so that its axis is not more than 0.2 cm at any point from the vertical axis of the vessel, and rotates smoothly without significant wobble. The stirring blade, 3.0 mm to 5.0 mm thick, forms a section of a circle having a diameter of 83 mm, and is subtended by a parallel chords of 42±1 mm and 75±1 mm. The blade passes through the diameter of the shaft so that the bottom of the blade is flush with the bottom of the shaft, and the blade is positioned horizontally at the end of the rotating shaft so that the 42-mm edge is nearest the lowest inner surface of the vessel. The distance of 2.5±0.2 cm between the blade and the inside bottom of the vessel is maintained during the test. The metallic blade and shaft comprise a single entity that may be coated with a suitable fluorocarbon polymer. The dosage unit is allowed to sink to the bottom of the vessel before rotation of the blade is started. A small, loose piece of nonreactive material such as wire or glass helix may be attached to dosage units that would otherwise float.

[4]A suitable paddle is available commercially from Hanson Research Corp. and from Van-Kel Industries.

Apparatus 1—The assembly[1] consists of the following: a covered, 1000 ml vessel made of glass or other inert, transparent material[2]; a variable-speed drive; and a cylindrical basket. The vessels are immersed in a suitable water bath of any convenient size that permits holding the temperature at 37°±0.5° C. during the test and keeping the bath fluid in constant, smooth motion. No part of the assembly, including the environment in which the assembly is placed, contributes significant motion; agitation, or vibration beyond that due to the smoothly rotating stirring element. Apparatus that permits observation of the specimen and stirring element during the test is preferable. The vessel is cylindrical, with a spherical bottom. It is 16 cm to 17.5 cm high, its inside diameter is 10.0 cm to 10.5 cm, and its nominal capacity is 1000 ml. Its sides are flanged near the top. A fitted cover may be used to retard evaporation.[3] The shaft is positioned so that its axis is not more than 0.2 cm at any point from the vertical axis of the vessel. A speed-regulating device is used that allows the shaft rotation speed to be selected and maintained at the rate specified in the individual monograph, within ±4%.

[1]A suitable vessel is available commercially as Kimble Glass No. 33730, from laboratory supply houses, or as Elanco Products Division No. EQ-1900, from Eli Lilly and Co., P.O. Box 1750, Indianapolis, Ind. 46206. A suitable basket is available commercially from Hanson Research Corp., P.O. Box 35, Northridge, Calif. 91324, and from Van Kel Industries, P.O. Box 311 Chatham, N.J. 07928.

[2]The materials should not sorb, react, or interfere with the specimen being tested.

[3]If a cover is used, it provides surricient openings to allow ready insertion of the thermometer and withdrawal of specimens.

Assay Procedure for Calcium:

At each dissolution time period 50.0 ml of dissolution media is removed from the vessel and replaced with 50 ml of gastric fluid without enzymes. The 50.0 ml aliqnot is transferred to a suitable container. The solution is made basic by addition of 15 ml of 1N sodium hydroxide. 300 mg of hydroxy napthol blue triturate is added and the resultant solution titrated with standardized 0.05 M disodium ethylenediaminetetraacetate until the solution is deep blue. Each ml of 0.05 M disodium ethylenediaminetetraacetate is equivalent to 5.004 mg of calcium carbonate.

Calculation for percent in solution

$$\frac{\text{mg } CaCO_3 \times 18}{1500} \times 100\% = \%\ \text{Ca in solution}$$

The invention being thus described, it will be obvious that the same may be varied in many ways. Such variations are not to be regarded as a departure from the spirit and scope of the invention and all such modifications are intended to be included within the scope of the following claims.

We claim:

1. A chewable mineral supplement having a penetration hardness of 2 mm or more which comprises:

from about 40 to about 85% by weight of a nougat candy base comprising:

a syrup component comprising:

(a) corn syrup having a dextrose equivalence from about 35 to about 55;

(b) sugar such that the ratio of sugar to corn syrup is from about 1:1 to about 2:1; a whipped component comprising at least one whipping agent which introduces air into the nougat candy base to lower its specific weight and modify its texture;

an edible polyol in an amount of from about 1.5 to about 6.0% by weight;

a mineral compound in an amount of about 3 to about 40% by weight; and

a water content of about 2 to about 4.5% by weight;

all percents herein are by weight of the final chewable mineral supplement.

2. The chewable mineral supplement of claim 1 wherein said nougat candy base comprises:

a syrup component in an amount of about 78 to about 99%, and

a whipped component in an amount of about 1 to about 22%; all percentages are by weight of the nougat candy base.

3. The chewable mineral supplement of claim 2 wherein said syrup component comprises: by weight of the chewable mineral supplement,

corn syrup in an amount of about 13 to about 41%,

sugar in an amount of about 15 to about 53% such that the ratio of sugar to corn syrup is from about 1:1 to about 2:1.

4. The chewable mineral supplement of claim 2 wherein said whipped component comprises: by weight of the chewable mineral supplement,

at least one whipping agent present in an amount of from about 0.1 to about 1%.

5. The chewable mineral supplement of claim 1 wherein said edible polyol is selected from the group consisting of propylene glycol, glycerin, polyethylene glycol and mixtures thereof.

6. The chewable mineral supplement of claim 1 wherein the edible polyol is glycerin.

7. The chewable mineral supplement of claim 1 wherein the edible polyol is present in an amount of from about 2.5 to about 4.5% by weight.